Claims 13-16, 19, and 20 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Zhu et al. U.S. Patent 6,287,322 (hereinafter "Zhu").

Claims 22 has been allowed.

Reconsideration and allowance of this application in light of the following remarks is hereby respectfully requested.

The Objections to the Specification

The specification has been objected to as failing to provide proper antecedent basis for the claimed subject matter. Particularly, the Examiner asserts on page 2, lines 3-5 that "the specification does not provide antecedent basis for the angle between the handle and the blade and the angle between the tip and the blade to be less than 180 degrees." Applicants respectfully disagree.

Applicants submit that the specification provides antecedent basis for the angle between the tip and the blade to be less than 180 degrees at least in the portion of the specification at page 5, lines 4-6 that states "[a]n angle between the blade portion and the tip portion may be less than 180°."

Moreover, applicants respectfully submit that the specification taken in conjunction with the figures provides sufficient antecedent basis for the angle between the handle and the blade to be less than 180 degrees. For example, with reference to FIG. 1, the portion of the specification at page 13, lines 28-31 states that "[h]andle 12 and blade 14 form an angle 22, and blade 14 and tip 16 form an angle 24. As described hereinabove, angles 22 and 24 may be adjusted to accommodate different target sites." Also, as described above, the portion of the specification at page 5, lines 4-6 states that "[a]n angle between the blade portion and the tip portion may be less than 180°." Applicants respectfully submit that these portions of the specification taken in conjunction with FIG. 1, which illustrates angle 22 formed between handle 12 and blade 14 as being less than 180 degrees, provides sufficient antecedent basis for the angle between the handle and the blade to be less than 180 degrees.

Applicants respectfully request, therefore, that the objections to the specification be withdrawn.

The Rejections Based on 35 U.S.C. § 102

As Anticipated by Nash

Claim 21 has been rejected under 35 U.S.C. § 102(b) as being anticipated by Nash.

Applicants' independent claim 21 defines apparatus for producing a hollow anastomotic connection between a first aperture in a side wall of a patient's body tissue conduit and a second aperture in a side wall of a graft conduit. The apparatus includes a first hollow annular connector configured for installation in the first aperture in the side wall of the body tissue conduit and a second hollow annular connector "configured for disposition annularly within the second aperture in the side wall of the graft conduit."

For example, as shown in applicants' FIG. 33, a second connector 400 may be encapsulated within an incision 454 "made in side wall 452 of graft 450," (applicants' specification, page 35, line 11). Second connector 400 and graft 450 may be attached to a first target vessel connector 100 installed in a target vessel 300, as shown in FIG. 37, to leave "side wall 452 of graft conduit 450 connected to sidewall 302 of target vessel 300 by enlarged connector 400," (applicants' specification, page 36, lines 27-29).

On page 2, lines 8-12 of the Office Action, the Examiner asserts that connectors 64 and 74 of Nash anticipate the apparatus of applicants' claim 21. Applicants respectfully disagree.

Nowhere does Nash show or suggest a first hollow annular connector configured for installation in the first aperture in the side wall of the body tissue conduit and a second hollow annular connector "configured for disposition annularly within the second aperture in the side wall of the graft conduit," as required by applicants' independent claim 21. Instead, Nash describes a system for creating an anastomoses of a "tubular organ within the body of a living being with another vessel . . . (e.g., a bypass graft). The one vessel . . . has a wall with an opening provided therein. The other vessel . . . has a free end portion," (Nash, column 2, lines 62-67, emphasis added).

For example, as shown in FIG. 11 of Nash, "the second connector member 64 is pre-mounted on the distal end of any desired vessel, duct, lumen or tubular organ," such as "within the open distal end of a saphenous vein bypass graft 10," (Nash, column 8, lines 39-44, emphasis added). Nowhere does Nash show or suggest making an anastomotic connection with a first connector and a second connector between "a first aperture in a side wall of a patient's body tissue conduit" and a "second aperture in a side wall of a graft conduit," as required by applicants' independent claim 21.

Thus, for at least the above reasons, applicants' independent claim 21 is allowable over Nash. Applicants respectfully request, therefore, that the rejection under 35 U.S.C. § 102(b) of independent claim 21, and any claims dependent therefrom, be withdrawn.

As Anticipated by Fugo

Claims 1-4 and 6 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Fugo.

Applicants' independent claim 1 defines apparatus for creating an incision having a controlled length in a side wall of a patient's body tissue conduit. The apparatus includes a tip portion having a sharpened free end portion configured for insertion into the side wall of the body tissue conduit to create a first hole and a second hole in the side wall. The apparatus also includes a blade portion attached to the tip portion, "wherein the blade portion is configured to create an incision between the first and second holes."

For example, as shown in applicants' FIGS. 2-5, a sharp tip portion 16 of tool 10 may create a first hole 34 and a second hole 36 in side wall 32, and a cutting blade 14 may create an incision 38 between first hole 34 and second hole 36 (see, e.g., applicants' specification, page 14, lines 1-19).

On page 2, lines 13-17 of the Office Action, the Examiner asserts that sharp tip 16 and blade 12 of Fugo anticipate the apparatus of applicants' claim 1. Applicants respectfully disagree.

Nowhere does Fugo show or suggest a sharpened free end portion of a tip portion configured to create "a first hole" and "a second hole" in a side wall, let alone a blade portion attached to the tip portion, "wherein the blade portion is configured to create an incision between the first and second holes," as required by applicants' independent claim 1. Instead, Fugo merely describes a surgical blade that sets a uniform depth for making an incision.

For example, as shown in FIG. 3, blade 28 of Fugo includes an active tip point 20 that is "used to puncture the sclera and the sclera is penetrated by the active tip 16 to a depth equal to the length of the active tip 16, creating a vertical sclera incision 22 of a known depth," (Fugo, column 4, lines 46-50). Then "a typical sclerostomy tunnel blade" (not shown in Fugo and certainly not blade 28) is used "to create a horizontal sclera tunnel . . . by extending an incision from the base of the vertical sclera incision 22," (Fugo, column 4, lines 54-57). Nowhere does Fugo show or suggest that active tip 16 creates two holes in a body tissue conduit for making an incision therebetween, and nowhere does Fugo show or suggest a blade portion attached to tip 16, "wherein the blade portion is configured to create an incision between the first and second holes," as required by applicants' independent claim 1.

Thus, for at least the above reasons, applicants' independent claim 1 is allowable over Fugo. Applicants respectfully request, therefore, that the rejection under 35 U.S.C. § 102(b) of independent claim 1, and any claims dependent therefrom, including claims 2-4 and 6, be withdrawn.

As Anticipated by Heisler

Claims 1, 2, 4, and 7 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Heisler.

As described above, applicants' independent claim 1 defines apparatus for creating an incision having a controlled length in a side wall of a patient's body tissue conduit. The apparatus includes a tip portion having a sharpened free end portion configured for insertion into the side wall of the body tissue conduit to create a first hole and a second hole in the side wall. The apparatus also includes a blade portion attached to the tip portion, "wherein the blade portion is configured to create an incision between the first and second holes."

On page 3, lines 1-6 of the Office Action, the Examiner asserts that Heisler's sharp tip 52 and blade 29 with sharp edge 38 of inner member 14 anticipate the apparatus of applicants' claim 1. Applicants respectfully disagree.

Nowhere does Heisler show or suggest a sharpened free end portion of a tip portion configured to create "a first hole" and "a second hole" in a side wall, let alone a blade portion attached to the tip portion, "wherein the blade portion is configured to create an incision between the first and second holes," as required by applicants' independent claim 1. Instead, Heisler is directed towards a surgical rotating shaver blade assembly.

Heisler's rotating shaver assembly includes an inner member 14 with a cutting edge 38 and sharp tip 52. Inner member 14 rotates within an outer tube 102 having a cutting edge 122, as shown in FIGS. 15 and 17 of Heisler. "[A]s the inner member rotates within the outer member, edge 38 intersects edge 122 . . . and facilitates the cooperative shearing action of the two cutting edges 38 and 122," (Heisler, column 8, lines 29-34). Nowhere does Heisler show or suggest that sharp tip 52 creates two holes in a body tissue conduit for making an incision therebetween, and nowhere does Heisler show or suggest a blade portion attached to the tip portion, "wherein the blade portion is configured to create an incision between the first and second holes," as required by applicants' independent claim 1.

Thus, for at least the above reasons, applicants' independent claim 1 is allowable over Heisler. Applicants respectfully request, therefore, that the rejection under 35 U.S.C. § 102(b) of independent claim 1, and any claims dependent therefrom, including claims 2, 4, and 7, be withdrawn.

As Anticipated by Taylor

Claims 8-11 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Taylor.

Applicants' amended independent claim 8 defines a method for creating an incision having a controlled length in a side wall of a body tissue conduit. The method includes creating a first hole in the side wall with a sharpened free end portion of a tip portion of a tool, wherein "the tip portion has a recessed portion that is configured to indicate a proper insertion depth of the tip portion into the side wall." After creating the first hole, the method also includes "advancing the tip portion into the body tissue conduit until the recessed portion is encapsulated by the side wall."

For example, as shown in applicants' FIGS. 1-5, a "tool 10 may include a recess 17 between tip 16 and blade 14 that indicates to a physician when tip 16 has been inserted far enough into a vessel," (applicants' specification, page 13, lines 22-24). As shown in applicants' FIG. 2, for example, "[t]ip 16 may be inserted through side wall 32 as far as recess 17," (applicants' specification, page 14, lines 3 and 4).

Nowhere does Taylor show or suggest a method for creating an incision using a tip portion that has "a recessed portion that is configured to indicate a proper insertion depth of the tip portion into the side wall," let alone a method that includes "advancing the tip portion into the body tissue conduit until the recessed portion is encapsulated by the side wall," as required by applicants' amended independent claim 8. Instead, Taylor describes a method of creating an incision wherein a surgeon can "visualize" the procedure and wherein the entry and exit points of the incision "can be observed visually," (Taylor, column 3, lines 58-66).

Taylor does not provide a recess in an incision tool for indicating a proper insertion depth because Taylor relies on the physician to visually determine the length of the tool portion inserted into the side wall. Moreover, nowhere does Taylor show or suggest a method that includes "advancing the tip portion into the body tissue conduit until the recessed portion is encapsulated by the side wall," as required by applicants' amended independent claim 8.

Thus, for at least the above reasons, applicants' amended independent claim 8 is allowable over Taylor. Applicants respectfully request, therefore, that the rejection under 35 U.S.C. § 102(b) of independent claim 8, and any claims dependent therefrom, including claims 9-11, be withdrawn.

As Anticipated by Zhu

Claims 13-16, 19, and 20 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Zhu.

Claims 13-16

Applicants' independent claim 13 defines apparatus for inserting a hollow annular connector into an aperture in a side wall of a body tissue conduit, wherein the apparatus includes a first anvil structure and a second anvil structure that are "configured for disposition within the hollow annular connector."

For example, as shown in applicants' FIG. 20, a delivery device 170 can include a first anvil structure 180 having a first elongated member 181 and a second anvil structure 182 having a second elongated member 183. "[A] connector such as connector 100 . . . may be disposed annularly around elongated members 181 and 183 of delivery device 170," and anvil structures 180 and 182 may be inserted into incision 304 such that "connector 100 has been encapsulated within incision 304," (applicants' specification, page 27, line 32 through page 28, line 13).

On page 3, lines 17-21 of the Office Action, the Examiner asserts that retractor halves 202a/202b, halves 308a/308b, halves 608a/608b, and/or levers 422 of Zhu anticipate the apparatus of applicants' independent claim 13. Applicants respectfully disagree.

Nowhere does Zhu show or suggest inserting a hollow annular connector into an aperture in a side wall of a body tissue conduit, let alone first and second anvil structures that are "configured for disposition within the hollow annular connector," as required by applicants' independent claim 13. Instead, Zhu describes various embodiments of a retractor that is used to provide a clip applicator with better access to a puncture site for closing a wound.

Halves 35a and 35b of Zhu's retractor 30, for example, as shown in FIGS. 7 and 8 of Zhu, separate such that "the patient's tissue is displaced laterally, allowing better access to the puncture site 25. . . [A] clip applicator 70 is advanced through the retractor 30" such that "surgical clips located at the distal tip of the clip applicator 75 are applied to the puncture wound 25," (Zhu, column 15, lines 1-10). Therefore, portions of Zhu's retractors (e.g., halves 202a/202b, halves 308a/308b, halves 608a/608b, and/or levers 422) separate to allow a wound closure instrument (such as a suture, not a hollow annular connector) to pass therethrough for closing a wound. However, nowhere does Zhu show or suggest inserting a hollow annular connector into an aperture in a side wall of a body tissue, and nowhere does Zhu show or suggest first and second anvil structures that are "configured for disposition within the hollow annular connector," as required by applicants' independent claim 13.

Thus, for at least the above reasons, applicants' independent claim 13 is allowable over Zhu. Applicants respectfully request, therefore, that the rejection under 35 U.S.C. § 102(b) of independent claim 13, and any claims dependent therefrom, including claims 14-16, be withdrawn.

Claim 19

Applicants' independent claim 19 defines apparatus for inserting a hollow annular connector into an aperture in a side wall of a body tissue conduit. The apparatus includes an expansion structure and a movable member attached to the expansion structure, wherein the movable member effects the movement of the expansion structure, and wherein "the movement of the expansion structure is configured to expand the connector in the axial direction of the body tissue conduit and in the radial direction of the body tissue conduit."

For example, as shown in applicants' FIGS. 20-23, a delivery device 170 can include a movable member or handle portion 172 that may be moved to effect the movement of a first anvil structure 180 having a first elongated member 181 and a second anvil structure 182 having a second elongated member 183. "[A] connector such as connector 100 . . . may be disposed annularly around elongated members 181 and 183 of delivery device 170," and anvil structures 180 and 182 may be inserted into incision 304 such that "connector 100 has been encapsulated within incision 304," (applicants' specification, page 27, line 32 through page 28, line 13). "To expand connector 100 in the axial direction of target vessel 300, handle portion 172 of device 170 may be pulled in direction 184 . . . and [t]o expand connector 100 in the radial direction of target vessel 300, handle portion 172 of delivery device 170 may be rotated in direction 176," (applicants' specification, page 28, lines 15-22).

On page 3, lines 17-21 of the Office Action, the Examiner asserts that retractor halves 202a/202b, halves 308a/308b, halves 608a/608b, and/or levers 422 of Zhu anticipate the apparatus of applicants' independent claim 19. Applicants respectfully disagree.

Nowhere does Zhu show or suggest inserting a hollow annular connector into an aperture in a side wall of a body tissue conduit, let alone a movable member that effects the movement of an expansion structure, wherein "the movement of the expansion structure is configured to expand the connector in the axial direction of the body tissue conduit and in the radial direction of the body tissue conduit," as required by applicants' independent claim 19. Instead, as described above, Zhu shows various embodiments of a retractor that is used to provide a clip applicator with better access to a puncture site for closing a wound. Halves 35a and 35b of Zhu's retractor 30, for example, as shown in FIGS. 7 and 8 of Zhu, separate from one another in a first direction to better allow access of surgical clips for closing a wound.

Therefore, portions of Zhu's retractors (e.g., halves 202a/202b, halves 308a/308b, halves 608a/608b, and/or levers 422) separate to allow a wound closure instrument (such as a suture, not a hollow annular connector) to pass therethrough for closing a wound. However, nowhere does Zhu show or suggest inserting a hollow annular connector into an aperture in a side wall of a body tissue, and nowhere does Zhu show or suggest that "movement of the expansion structure is configured to expand the connector in the axial direction of the body tissue conduit and in the radial direction of the body tissue conduit," as required by applicants' independent claim 19.

Thus, for at least the above reasons, applicants' independent claim 19 is allowable over Zhu. Applicants respectfully request, therefore, that the rejection under 35 U.S.C. § 102(b) of independent claim 19, and any claims dependent therefrom, be withdrawn.

Claim 20

Applicants' independent claim 20 defines apparatus for holding open an incision in a patient's body tissue conduit. The apparatus includes first and second incision members and first and second end portions, "wherein the first and second incision members are configured for insertion into the incision by compressing the first and second end portions."

For example, as shown in applicants' FIGS. 25 and 26, an incision structure 320 can include end portions 322 that may each have an incision member 324 for holding open an incision 332 in a target vessel 330. Incision structure may hold open incision 332 "by compressing end portions 322 toward one another such that both incision members 324 enter the incision," (applicants' specification, page 30, lines 16-18).

On page 3, lines 17-21 of the Office Action, the Examiner asserts that retractor halves 202a/202b, halves 308a/308b, halves 608a/608b, and/or levers 422 of Zhu anticipate the apparatus of applicants' independent claim 20. Applicants respectfully disagree.

Nowhere does Zhu show or suggest apparatus for holding open an incision in a patient's body tissue conduit, let alone such apparatus that includes first and second incision members "configured for insertion into the incision by compressing the first and second end portions," as required by applicants' independent claim 20. Instead, as described above, Zhu shows various embodiments of a retractor that is used to provide a clip applicator with better access to a puncture site for closing a wound. Halves 35a and 35b of Zhu's retractor 30, for example, as shown in FIGS. 7 and 8 of Zhu, separate from one another in a first direction to better allow access of surgical clips for closing a wound.

Therefore, Zhu is directed towards closing incisions by using retractors (e.g., halves 202a/202b, halves 308a/308b, halves 608a/608b, and/or levers 422) that separate to allow a wound closure instrument to pass therethrough for closing a wound. However, nowhere does Zhu show or suggest apparatus for holding open an incision in a patient's body tissue conduit, and nowhere does Zhu show or suggest such apparatus for holding open an incision that includes first and second incision members "configured for insertion into the incision by compressing the first and second end portions," as required by applicants' independent claim 20.

Thus, for at least the above reasons, applicants' independent claim 20 is allowable over Zhu. Applicants respectfully request, therefore, that the rejection under 35 U.S.C. § 102(b) of independent claim 20, and any claims dependent therefrom, be withdrawn.

Conclusion

The foregoing demonstrates that claims 1-4, 6-11, and 13-22 are allowable. This application is therefore in condition for allowance. An early and favorable action is respectfully requested.

Respectfully submitted,

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